

K083421

GE Healthcare

MR-Touch™ Option for GE Signa® MR Systems
510(k) Premarket Notification

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92.

JUL 24 2009

Submitter: GE Medical Systems, LLC
3200 N. Grandview Blvd.
Waukesha, WI 53188

Contact Person: Daniel T. Biank
Regulatory Affairs Leader

Telephone: 262 - 521 - 6467

Fax: 262 - 521 - 6379

Email: Daniel.Biank@med.ge.com

Date Prepared: November 12, 2008

Device Name:

Proprietary Name: MR-Touch™ Option

Common Name: Software and Hardware Accessory for Magnetic Resonance Imaging System

Classification Name: Magnetic Resonance Diagnostic Device, (21 C.F.R. 892.1000, LNH)

Predicate Devices:

GE 1.5T and 3.0T Signa® HDx MR System (K052293).

Ultrasonix SonixTouch Ultrasound Imaging System for Elastography (K083095).

Device Description:

MR-Touch™ is a combined software and hardware accessory for use with a GE Signa® MR System. It is an evolutionary improvement of the existing phase-contrast imaging feature included with existing GE Signa® MR Systems. The Resoundant hardware component consists of an acoustic wave generator coupled through a length of flexible tubing with a passive transducer to induce small vibrations in the scan subject. The software includes both image acquisition and reconstruction components. The acquisition software is a gradient echo sequence that acquires a series of phase-contrast images over time. It also synchronizes the low frequency and low magnitude induced vibrations generated by Resoundant. The phase-contrast imaging technique measures motion or displacement. During reconstruction, the displacement from the induced vibrations is detected using the time-series of phase-contrast images. MR-Touch™ then presents the reconstructed displacement information as strain wave and relative stiffness images (referred to as Elastograms).

Intended Use:

MR-Touch™ is a software and hardware option intended for use with GE Signa® MR systems. It is indicated for magnetic resonance imaging of the human body.

MR-Touch™ generates transverse sectional information related to the relative stiffness of soft tissue. It consists of hardware as well as acquisition and reconstruction software. The hardware components induce vibrations into the scan subject. The MR-Touch™ acquisition software is an evolutionary improvement to the gradient echo sequence. The sequence synchronizes the induced vibrations to acquire a series of phase-contrast images over time. The phase-contrast imaging technique measures motion or displacement. The displacement from the induced vibrations is detected using the time-series of phase-contrast images. The displacement information is reconstructed and presented as strain wave and relative stiffness images.

When used with a GE Signa® MR system, MR-Touch™ is capable of producing transverse images of internal body structures such as muscle and liver.

When interpreted by a trained physician, these images may provide information that can be useful in determining a diagnosis.

Comparison with Predicate Devices:

MR-Touch™ is substantially equivalent to the existing phase-contrast imaging feature of the previously cleared GE 1.5T and 3.0T Signa® HDx MR System (K052293). The primary differences include a more convenient method to visualize a time-series of phase-contrast images and the ability to induce synchronized vibrations in the scan subject during acquisition. The Elastography relative-stiffness images (Elastograms) are substantially equivalent to the output of the previously cleared Ultrasonix SonixTouch Elastography imaging mode, which provides color-coded images to differentiate between tissues based on stiffness.

Summary of Studies:

MR-Touch™ has been verified to function with the GE Signa® HDx MR System. Sample images demonstrate the strain wave and Elastogram outputs. Additionally, included confidence studies prove that MR-Touch™ produces repeatable results and can reliably differentiate between tissues of different stiffness.

The Resoundant, new hardware introduced with MR-Touch™, has been evaluated to the appropriate clauses of IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety standard and IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety 2001 - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests - Second Edition with Amendment 1.

Conclusion:

It is the opinion of GE that MR-Touch™ when used with a GE Signa® MR System is substantially equivalent to the currently cleared and marketed GE 1.5T and 3.0T Signa® HDx MR Systems, providing Elastography image output that is substantially equivalent to the output provided by the Elastography imaging mode of the currently cleared Ultrasonix SonixTouch Ultrasound Imaging System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Daniel Biank
Regulatory Affairs Leader
GE Healthcare, MR
3200 N. Grandview Blvd.
WAUKESHA WI 53188

JUL 24 2009

Re: K083421

Trade/Device Name: MR-Touch™ Option
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: June 23, 2009
Received: June 25, 2009

Dear Mr. Biank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

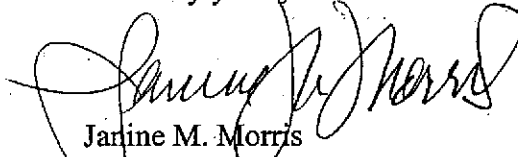
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K083421

Device Name:

MR-Touch™ Option

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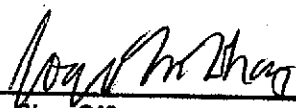
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Prescription Use X AND/OR Over-the-Counter Use
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

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